IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

WYETH, Plaintiff,	
v.	Civil Action No.: 06-222 JJF
IMPAX LABORATORIES, INC., Defendant.	**PUBLIC VERSION**

OPENING BRIEF OF DEFENDANT IMPAX LABORATORIES, INC. IN SUPPORT OF MOTION TO MODIFY SCHEDULING ORDER

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TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page

I. NATURE AND STAGE OF PROCEEDINGS

This case for patent infringement was brought by Plaintiff Wyeth to prevent Defendant Impax Laboratories, Inc. ("Impax") from bringing to market a generic version of Wyeth's EFFEXOR® XR product, which is a formulation of the anti-depressant medication venlafaxine hydrochloride.[1] (D.I. 1). The Court issued a Rule 16 Scheduling Order on July 13, 2006, *inter alia*, setting August 10, 2006 as the deadline to amend pleadings. (D.I. 27 ¶ 5). Impax brings this motion to request a minor modification to the Scheduling Order moving the date to amend pleadings back to March 30, 2007.

II. SUMMARY OF ARGUMENT

Impax has been diligent in investigating whether it may have further defenses or counterclaims prior to the August 10 deadline. Indeed, this investigation has revealed that the patents-in-suit should be held unenforceable for inequitable conduct. By stipulation of the parties, Impax has filed an Amended Answer and Counterclaims asserting this new defense and counterclaim.

Unfortunately, Impax has been forced to undertake its investigation based solely on information in the public record. This is because Wyeth is using the early August 10, 2006 deadline, along with its needless delay in producing key documents, as a shield to prevent Impax from timely investigating and asserting additional potential defenses and counterclaims. Wyeth has refused Impax's requests to either extend the deadline for amending pleadings or to produce the documents Impax needs to complete its investigation in advance of that deadline.

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[1] The patents-in-suit are U.S. Patent No. 6,274,171 ("'171 patent"), U.S. Patent No. 6,403,120 ("'120 patent"), and U.S. Patent no. 6,419,958 ("'958 patent"). Wyeth alleges patent infringement under 35 U.S.C. § 271(e)(2)(A) by reason of Impax's submission to the Food and Drug Administration ("FDA") of Abbreviated New Drug Application ("ANDA") No. 78-057.

Impax's investigation of the facts available in the public record has revealed that there may be at least one additional theory of inequitable conduct available to Impax.[2] In order to substantiate facts necessary to plead with particularity inequitable conduct under this theory, however, Impax must obtain discovery from Wyeth. For example, Impax must obtain data from experiments Wyeth undertook in conceiving and reducing to practice its alleged inventions and in support of the New Drug Application ("NDA") it submitted to the FDA. In the absence of sufficient time (or underlying documents) to take depositions of Wyeth and the inventors of the patents-in-suit, Impax further requires transcripts of depositions of those inventors and Wyeth's 30(b)(6) witnesses taken in the Teva Litigation.

All such documents were requested by Impax on June 23 and 30, 2006. Impax has been unable to obtain this discovery, however, because Wyeth has thrown up numerous barriers to delay the production of documents. For example, Wyeth has refused to produce any transcripts or pleadings from the Teva Litigation unless and until *Teva* redacts documents that *Wyeth* designated as confidential in that litigation. Wyeth has refused to produce electronic documents in their native format, insisting on producing only images or paper copies of documents with all of the crucial and discoverable metadata stripped away. Wyeth has refused to produce *any* documents unless Impax agrees to bear the entire cost of Wyeth's document production and half the cost of producing documents that were already gathered and processed for production in the Teva Litigation.

In an attempt to meet the August 10 deadline, Impax has proposed numerous compromises to facilitate the speedy production of documents, including an offer to pay

[2] The public record includes papers filed in Wyeth's lawsuit on the same patents against the generic manufacturer Teva Pharmaceuticals in the District of New Jersey, Civil Action No. 03-1293 (FSH) ("Teva Litigation").

for the paper production by August 4 of a limited subset of documents that plainly do not contain Teva confidential information. Wyeth rejected that offer and to date has only agreed to produce on a "rolling basis" the NDA for its commercial product Effexor® XR, obliging Impax to file a motion to compel in conjunction with the instant motion.

In order to allow Impax a fair opportunity to obtain and review discovery materials, to take depositions in support of this additional potential theory of inequitable conduct, and to investigate other potential defenses and counterclaims, Impax respectfully requests that the Court set March 30, 2007 as the deadline for the amendment of pleadings, which is the deadline set by the Court for joinder of third parties. Wyeth will not be prejudiced by this extension. This March 30, 2007 deadline will leave almost six months before expert reports are due. Moreover, this modification will not affect any of the other dates in the Court's Scheduling Order and will not delay the bringing of this case to trial.

III. STATEMENT OF FACTS

A. Wyeth sues Impax for patent infringement.

On February 21, 2006, Impax wrote Wyeth to inform it that it had submitted to the FDA an ANDA seeking approval to release venlafaxine hydrochloride extended-release formulations for treatment of depression. Declaration of Mary B. Matterer in Support of Impax's Motion to Modify Scheduling Order and Motion to Compel ("Matterer Decl."), Ex. 1. Impax informed Wyeth that its generic formulation would not infringe the patents-in-suit because it would not employ the extended release formulation claimed in Wyeth's patents, i.e., those including spheroids of microcrystalline cellulose. *Id.* at 3. Rather than employing a spheronization process, Impax's formulation would contain sugar spheres coated with a layer of venlafaxine hydrochloride covered with a sustained-release coating. *Id.* Not only do most of the claims of the patents-in-suit explicitly require microcrystalline cellulose, but in the Teva Litigation, the District of

New Jersey construed *every* claim of the patents-in-suit as requiring the presence of microcrystalline cellulose. (D.I. 7, Ex. A).[3]

Nonetheless, Wyeth initiated this suit for patent infringement against Impax on April 5, 2006, seeking to further delay or block from the market generic competition for its Effexor® XR product. (D.I. 1). Impax answered the Complaint on April 25, 2006. (D.I. 7).

B. Impax's investigation uncovers facts supporting a claim that the patents-in-suit are unenforceable for inequitable conduct.

At the time Wyeth filed its complaint, Impax's investigation had already revealed that Wyeth's patents were unenforceable due to Wyeth's unclean hands in asserting patents it knows are not infringed. (D.I. 7 ¶¶ 58-59, 67-69). Further investigation has revealed additional grounds for the unenforceability of these patents – Wyeth's inequitable conduct during prosecution before the PTO.

In summary, Impax has discovered that Wyeth committed inequitable conduct by misrepresenting to the PTO that "Venlafaxine ER showed a statistically significant improvement [in incidence of nausea] over conventional venlafaxine hydrochloride tablets in two eight-week and one 12 week clinical studies." Matterer Decl., Ex. 2 at 3 (Excerpt from U.S. Patent Application No. 60/014,006). In fact, the studies cited showed no such thing, as Impax has pled in its Amended Answer and Counterclaims, filed herewith by stipulation of the parties. First Amended Answer, Affirmative Defenses, Counterclaims, and Prayer for Relief of Defendant Impax Laboratories, Inc. ("Amended Answer") ¶¶ 66-67. Wyeth committed a further act of inequitable conduct because it withheld from the PTO an article revealing that in one of the controlled studies relied upon by Wyeth, the incidence of nausea was exactly the same in the two groups tested –

[3] In the wake of this unfavorable claim construction, Wyeth settled the Teva litigation, and the District of New Jersey vacated its claim construction opinion.

45%. Matterer Decl., Ex. 3 at 161 (Lynn A. Cunningham, M.D. "Once-Daily Venlafaxine Extended Release (XR) and Venlafaxine Immediate Release (IR) in Outpatients with Majory Depression, 9 ANNALS OF CLINICAL PSYCHIATRY 157 (1997) ("Cunningham Article")); Amended answer ¶¶ 76-80.

Impax has been able to plead this theory of inequitable conduct with particularity based solely on information in the public record. However, Wyeth's investigation has also revealed that, in the Teva Litigation, Teva asserted at least one further theory of inequitable conduct. Matterer Decl., Ex. 4 at at 1 n.3 (Order of the Honorable Magistrate Judge Patty Shwartz of 3/23/05). Because a large number of documents were designated as confidential or filed under seal in the Teva Litigation, however, and because Wyeth has refused to produce these documents – as well as other documents necessary to Impax's investigation – prior to the August 10 deadline to amend pleadings, Impax is not in a position to investigate whether this second theory of inequitable conduct is sound. Wyeth's delay in producing documents has also deprived Teva of the opportunity to investigate whether it may have additional claims or defenses.

C. Wyeth refuses to produce documents in time for the August 10 deadline to amend pleadings and refuses to stipulate to an extension of that deadline.

Impax has been diligent in attempting to obtain the documents it requires from Wyeth in advance of the August 10 deadline. Impax propounded document requests on Wyeth on June 23 and June 30, 2006, well before the Court issued its July 13 Scheduling Order. Matterer Decl., Exs. 5, 6.

Rather than cooperate in discovery, Wyeth is attempting to exploit the early August 10 deadline, by substantially stalling discovery until after the deadline. Wyeth has done this by taking numerous unreasonable positions regarding the scope of its discovery obligations and refusing to compromise on any of them:

- Wyeth refused to produce pleadings and transcripts from the Teva litigation on the grounds that "Teva has designated the bulk of this information as confidential and subject to the protective order in place in the Teva litigation, and it would be unduly burdensome to attempt to redact this information." Matterer Decl., Ex. 7 at 11, Ex. 8 at 26. Wyeth has taken this position even with regard to documents that are demonstrably *not* Teva confidential (such as the deposition transcripts of their own inventors and 30(b)(6) witnesses) and to date has produced not a single page of these documents.

- Wyeth insists that Impax bear the entire cost of its document production, despite the fact that it initiated this lawsuit and is a much larger company with greater resources. With regard to the documents it produced in the Teva Litigation (of which there are a whopping 1.3 million), for which it has already born the cost of gathering and preparing for production, Wyeth insists that Impax pay for half the cost of this production on the grounds that "Impax should not receive a windfall by receiving images of documents produced in a prior litigation free of cost." Matterer Decl, Ex. 9 at 4 (Letter from Wadler to Kassabian of Aug. 3, 2006).

- Wyeth refuses to produce documents in their native, electronic format. Instead, Wyeth will only produce documents as TIFF images or as paper copies, such that crucial and discoverable metadata that would facilitate the speedy review of documents – e.g., authors, recipients, date, and type of document – is stripped away. Matterer Decl., Ex. 10 at 3 (Letter from Kassabian to Wadler of July 24, 2006). Wyeth will not compromise on this position despite the fact that the case law and the newly Amended Federal Rules of Civil Procedure contemplate production of documents in native format or another format so that this metadata is included. *Williams v. Sprint/United Mgmt. Co.*, 230 F.R.D. 640, 644 (D. Kan. 2005); Matterer Decl., Ex. 27 at Rule 26(b)(2)(B).

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- Wyeth has imposed a geographical limitation on its discovery obligations, insisting that it will only produce documents from "its principal offices and pharmaceutical product research and development facilities in the United States," even though one of the central clinical studies in support of Wyeth's NDA for Effexor® XR took place in Europe. Matterer Decl., Ex. 7 at 2, Ex. 13 at 1 (Letter from Kassabian to Wadler of 7/31/06).

- Wyeth insists on a self-imposed cut-off date on its discovery obligations, refusing to produce documents, except in certain discrete categories it has defined itself, that were generated after February 10, 2003. Matterer Decl., Ex. 7 at 5.

Impax's position is that there is no basis for the limitations and conditions on discovery on which Wyeth is insisting, as detailed in Impax's Motion to Compel filed in concordance with this motion. Regardless of how these disputes are ultimately resolved, however, it became clear to Impax early in the discovery process that Wyeth's uncompromising positions threatened to delay the production of *any* documents until after the expiration of the August 10 deadline for amending pleadings. Accordingly, immediately after the Court issued its Scheduling Order, Impax requested that Wyeth agree to stipulate to a modification of the Scheduling Order to give the parties time to resolve these disputes. Wyeth has repeatedly refused to agree to an extension to alleviate the prejudice caused by Wyeth's dilatory conduct. Matterer Decl., Ex. 14 at 2, Ex. 15 at 3.

D. Wyeth rejects all offers to compromise to facilitate production prior to the August 10 deadline.

Impax has attempted to compromise the discovery disputes Wyeth has generated in an attempt to receive at least a limited production of documents in advance of the August 10 deadline. Wyeth has consistently rejected compromise.

Anticipating delay for production of the Teva Litigation pleadings and transcripts due to the possibility that Teva had designated portions of some of these documents as confidential, Impax requested the production of these documents with those portions of the documents redacted that were designated as confidential by Teva. *See, e.g.*, Matterer Decl., Ex. 5 at 5. Wyeth objected to producing redacted transcripts or pleadings from the Teva litigation, stating

> Teva has designated the bulk of this information as confidential and subject to the protective order in place in the Teva litigation, and it would be unduly burdensome to attempt to redact this information. Moreover, under the protective order in place in that litigation, Teva, not Wyeth, would have to redact information it designated as confidential.

Matterer Decl., Ex. 7 at 11, *see also id.*, Ex. 8 at 26.

Impax informed Wyeth that it was not seeking Teva confidential information. Matterer Decl., Ex. 13 at 2-3. Rather, Impax sought such things as Wyeth's inventor and 30(b)(6) deposition testimony and Wyeth's experimental data and documents concerning the development of the patented inventions and the prosecutions of the patents-in-suit – documents highly unlikely to contain Teva confidential information. Moreover, contrary to Wyeth's assertion, there is no provision in the protective order entered in the Teva Litigation that only Teva has the ability or authority to redact Teva confidential information in a subsequent litigation such as this. *Id.* Wyeth has not only the ability but also the obligation to produce in this lawsuit all requested documents in its possession which are relevant, as these documents unquestionably are. If a protective order in the Teva Litigation requires that some material be redacted, Wyeth knows what Teva has designated and can redact it. Moreover, there is no excuse whatsoever for withholding documents from the Teva Litigation which have not been designated as confidential by Teva. Wyeth should have produced these documents already.

Wyeth nonetheless refused to produce documents from the Teva Litigation, including documents containing only Wyeth confidential information. As justification, Wyeth stated that "[y]ou further acknowledge the difficulty of identifying with particularity the information – whether of Wyeth or Teva – deemed by Teva to be confidential." Matterer Decl., Ex. 12 at 4 (Letter from Wadler to Kassabian of 8/1/06). Any difficulty that Impax would have in identifying which documents contained Teva confidential information was of course not applicable to Wyeth – Wyeth has the documents in its possession and can easily identify which ones were designated by Teva as confidential.

Nonetheless, Impax proposed sending a list of documents to Teva, so that it could indicate which ones it considered confidential. Matterer Decl., Ex. 13 at 3. Wyeth would then be able to produce the documents not designated by Teva as confidential pending

agreement on a redaction process for the Teva confidential documents. To facilitate this process, Impax requested that Wyeth provide a list of pleadings and deposition and hearing transcripts generated from the Teva litigation. *Id.* Wyeth refused this request on the basis that "this information is publicly available from the Court's docket." Matterer Decl., Ex. 12 at 4. This, of course, is not true. Deposition and hearing transcripts are not listed on the docket for the Teva Litigation and there is no indication as to the identity of declaration exhibits filed under seal. Moreover, it appears that certain pleadings were lodged with the Court and not entered in the public docket.

Nonetheless, Impax has diligently attempted to move forward with its plan, sending a letter to Teva's counsel containing a small list of documents from the Teva litigation and asking if Teva would verify whether or not each document was designated by Teva as containing Teva confidential information. For those documents that were designated by Teva as containing Teva confidential information, Impax requested that Teva indicate which portions should be redacted. Matterer Decl., Ex. 17 (Letter from Matterer to Dinger of 8/1/06). Due to Wyeth's refusal to produce even those documents that clearly contained only Wyeth confidential information, Impax was forced to list such documents as the deposition transcripts of Wyeth's 30(b)(6) witnesses and the inventors of the patents-in-suit. *Id.* Teva's counsel responded to Impax's letter on Friday August 4 indicating that Teva would respond to Impax's request the following week. Matterer Decl., Ex. 18 (Letter from Dinger to Matterer of 8/4/06). To date, Teva has not provided a substantive response. Accordingly, this process has not resulted in a solution to the barrier Wyeth has erected to the production of any Teva Litigation pleadings or transcripts prior to the August 10 deadline.

As an attempt at further compromise, Impax requested that Wyeth produce a limited subset of documents from the Teva Litigation by Friday, August 4 that clearly would not contain Teva confidential information: the transcripts of the inventors of

Wyeth's patents-in-suit and 30(b)(6) witnesses and the Proposed Amended Answer submitted by Teva in support of a motion for leave to amend. Matterer Decl., Ex. 19 at 1 (Letter from Ernst to Wadler of 7/31/06). As a further attempt at compromise, Impax offered that "in order to expedite the production of these documents, Impax is willing to set aside the parties' current disagreements regarding the format and costs of document productions. Specifically, Impax is willing to accept paper copies of these documents and to pay for the reasonable cost of producing these documents." *Id.* at 2.

On August 2, Wyeth refused to produce even this small subset of documents by August 4. Matterer Decl., Ex. 15 (Letter from Wadler to Ernst of 8/2/06). As a basis for refusing to produce Teva's Proposed Amended Answer in the Teva litigation, Wyeth stated that "it was filed under seal subject to the protective order in that litigation by Teva. As a result, we cannot provide you with such information without getting approval from Teva." *Id.* at 3. Teva's motion to file this document under seal in the Teva litigation demonstrates that Wyeth's assertion is mere pretext for its refusal to produce this document. Teva moved to file its Proposed Amended Complaint under seal in the Teva litigation because "[t]he materials that Defendants seek to seal include documents and information designated as 'confidential' by *Plaintiff*," i.e., by Wyeth, not Defendant Teva. Matterer Decl., Ex. 20 ¶ 3 (Certification of Michael E. Patunas of Apr. 1, 2005) (emphasis added); Ex. 21 at 2 (Letter from Ernst to Wadler of 8/4/06). Accordingly there is nothing to prevent Wyeth's immediate production of this document as confidential pursuant to D. Del. LR 26.2.

On August 2, Wyeth finally agreed that it would produce the deposition transcripts of its inventors and 30(b)(6) witnesses, but not in time to meet the August 10 deadline. Wyeth stated that the Court's schedule "does not envision document production to be completed until October 10, 2006, notwithstanding the earlier date for amendment of pleadings." Matterer Decl., Ex. 15 at 2. Even so, the schedule does not

give Wyeth the right to withhold documents timely requested and readily producible in order to avoid amendment of the pleadings. To ensure the production of these transcripts after the August 10 deadline, Wyeth further stated that "[i]n light of Impax counsel's August 1, 2006 letter to Teva Counsel, Henry Dinger, asking whether the deposition transcripts of the named inventors, Dr. Mangano and Mr. Alaburda contain Teva confidential information, we will wait to hear Teva's response before production of those deposition transcripts." *Id.* at 2 n.1. Wyeth, of course, knows if the deposition transcripts of its own named inventors contain Teva confidential information. They almost certainly do not. To date, Wyeth has not produced the transcripts. Wyeth's refusal to produce the transcripts pending confirmation from *Teva* as to this fact can only be viewed as an attempt to delay production past the August 10 deadline.

In addition to the limited subset of documents from the Teva litigation listed above, Impax further requested Wyeth's NDA for Effexor® XR and the data underlying the experiments contained therein on an expedited basis. Matterer Decl., Ex. 19 at 1. Specifically, Impax requested production of the NDA by Friday, August 4. Impax made clear that its offer to pay for the cost of production was expressly contingent on Wyeth producing the NDA by Friday, August 4, so that Impax would have the opportunity to analyze it prior to the August 10 deadline. *Id.* at 2. In reply, Wyeth refused to produce any documents by Friday August 4, stating that this request was "not reasonable." Matterer Decl., Ex. 15 at 2. At the same time, Wyeth purported to "accept [Impax's] offer to pay for paper copies for production documents from Wyeth's NDA No. 20-699." *Id.* Rather than produce its NDA on the expedited basis requested by Impax, however, Wyeth would only produce it as a "rolling production." Matterer Decl., Ex. 22 at 2 (Letter from Wadler to Kassabian of 8/4/06). Subsequently, Wyeth began producing the NDA a few boxes of documents at a time in a manner calculated to deprive Impax of the opportunity to analyze the information in time for the August 10 deadline. The most

recent installment was received on August 8, two days before the deadline – thirteen boxes of paper not as kept in the ordinary course of business or as submitted to the FDA, but as an unorganized mass of paper again calculated to deprive Impax of the opportunity for meaningful analysis in the two days remaining before the August 10 deadline. Matterer Decl., Ex. 23 (Letter from Pollock to Kassabian of 8/8/06).

There is no justification for Wyeth's producing its NDA in a "rolling production." Despite the length of the NDA, it has already been gathered and processed for production in the Teva Litigation and can be produced in one day in one package, as images burned onto a compact disc. This is evidenced by the fact that Impax produced its own ANDA to Wyeth in one package on Friday August 4. Matterer Decl., Ex. 24 (Letter from Kassabian to Wadler of 8/4/06).

Impax's offer to pay for production of the limited subset of documents was expressly contingent on Wyeth's agreement to produce them by August 4. Wyeth's response to Impax's offer to compromise – that it would not produce the small subset of documents on an expedited basis, but would nevertheless accept Impax's offer to pay for this production – has convinced Impax that Wyeth is manufacturing needless discovery disputes in an attempt to prevent Impax from discovering the information it requires in time to meet the August 10 deadline. Matterer Decl., Ex. 25 at 1-2. Accordingly, Impax was left with little choice but to bring this motion, requesting the Court to change the August 10 deadline.

IV. ARGUMENT

Impax respectfully requests that the Court modify the Scheduling Order to make March 30, 2007 the deadline for amending pleadings.

A scheduling order may be modified "upon a showing of good cause and by leave of the district judge." FED. R. CIV. P. 16(b). A modification is warranted here because

discovery has only just commenced in this case. With the exception of Impax's production of its ANDA and the beginning of Wyeth's "rolling production" of its NDA, no documents have been exchanged. Further, the parties have not had the opportunity to conduct depositions, and expert reports are not due to be exchanged until September 28, 2007, over a year from now. The parties should have a fair opportunity to pursue discovery in order fully to investigate potential additional claims or defenses that may be available. Particularly with regard to claims and defenses that must be pled with particularity, such as inequitable conduct, the requirement to seek amendment before substantial discovery has occurred presents a substantial barrier to Impax's ability to assert all viable defenses to Wyeth's claims of patent infringement.

Although the August 10 deadline occurs less then one month after the scheduling order was entered, Impax did not wait until the entry of that order to begin its pursuit of its discovery and has been diligent in attempting to pursue that discovery in time to investigate all potential defenses in advance of the August 10 deadline. However, Wyeth's lack of cooperation has made it impossible to obtain the necessary production as quickly as the Scheduling Order contemplates. Moving back the deadline to amend pleadings will provide the parties time to resolve these discovery disputes in advance of the amendment of pleadings but in plenty of time before the scheduled Markman hearing, expert discovery, and trial.

Nor can Wyeth claim any prejudice by this modification to the Scheduling Order. It is already knowledgeable about the facts relating to its conduct before the PTO, and will be afforded the same opportunity for discovery as Impax. During meet and confer, Wyeth was able to articulate no prejudice it would incur if the deadline were moved back, stating only that "[t]he Scheduling Order reflects the Court's views as to how the case should be managed." Matterer Decl., Ex. 15 at 3. Impax respectfully suggests that the

Scheduling Order is not intended to reward Wyeth for withholding documents in order to preclude the timely pleading of all viable defenses and counterclaims.

V. CONCLUSION

For the foregoing reasons, Impax respectfully requests that the Court modify the Scheduling Order to set March 30, 2007 as the deadline for amending pleadings.

Dated: August 10, 2006

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CERTIFICATE OF SERVICE

I hereby certify that on the 15th day of August, 2006, I electronically filed the foregoing document, **PUBLIC VERSION OF OPENING BRIEF OF DEFENDANT IMPAX LABORATORIES, INC. IN SUPPORT OF MOTION TO MODIFY SCHEDULING ORDER**, with the Clerk of the Court using CM/ECF which will send notification of such filing to the following:

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Additionally, I hereby certify that on the 15th day of August, 2006, the foregoing document was served as indicated on the following:

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